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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 09/781,388 | 02/13/2001 | Daniel Keith Tomaschko | S63.2-9711 | 2245 |

490 7590 01/12/2004

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

BUI, VY Q

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3731

19

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/781,388

Applicant(s)

TOMASCHKO ET AL.

Examiner

Vy Q. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-30, 33-39, 41-43, 45 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

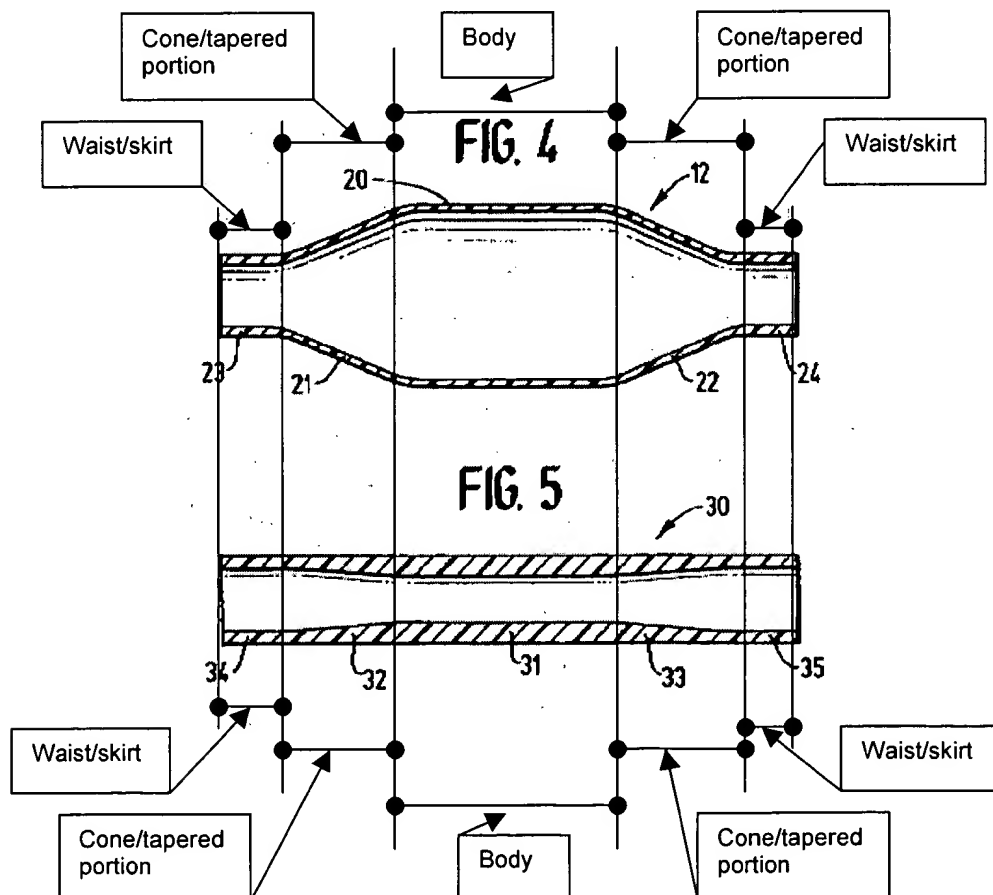
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 27-30 are rejected under 35 U.S.C. 102(b) as anticipated by WAND et al. (US Pat. 5,525,388).



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As to claims 27-29, WAND (Figs. 4-5 above; column 2, lines 16-22) discloses balloon 12 having cone portions and body portion of a same wall thickness which has a variation less than 20% of a nominal or average wall thickness over substantially the entire length of the balloon. Since the wall thickness variation is about 20%, the cone wall thickness can be up to 20 % less than the body wall thickness. Balloon 12 has ground surfaces because the cone portions of balloon 12/parison 12 are thinned by machining, abrading or other suitable means (see WAND, col. 2, lines 45-53).

As to claim 30, balloon 12 has a constant thickness over substantially the entire length of the balloon because the waist portions are relatively short in comparison to the body and cone portions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 33-39, 42-43 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over WAND et al. (5,525,388) in view of NODDIN et al (4,906,241).

WAND discloses substantially all limitations in the claims, except for the thickness of the waist portions is no thicker than the thickness of the cone portions or body portion. However, NODDIN (Figs. 1 and 9a; col. 6, lines 21-26; col. 8, lines 43-54) discloses balloon 12 with cone/transition portions 54/56 of wall thickness $t_{sub.t}$, body portion of wall thickness $t_{sub.b}$ and waist portions 58/60 of wall thickness t substantially the same or $t_{sub.t}$ thinner than $t_{sub.b}$ for a low profile balloon catheter suitable for a small lumen. In view of NODDIN, it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove the material of the WAND parison/balloon by machining or abrading the waist portions of WAND balloon in order to have the thickness of the waist portions being no thicker than the thickness of the body portion as claimed so that the catheter can be suitable for a small lumen. Notice that NODDIN provides one of ordinary skill in the art the motivation to modify WAND balloon to have

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the features as claimed because WAND does not require the waist portions being thinner than the cone portions or body portion.

2. Claims 41 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over NODDIN et al (4,906,241) in view of RAU et al. (6,024,722).

NODDIN (Figs. 1 and 9a; col. 6, lines 21-26; col. 8, lines 43-54) discloses balloon 12 with cone/transition portions 54/56 of wall thickness $t_{sub.t}$, body portion of wall thickness $t_{sub.b}$ and waist portions 58/60 of wall thickness t substantially the same or $t_{sub.t}$ thinner than $t_{sub.b}$ for a low profile balloon catheter suitable for a small lumen. NODDIN does not disclose a balloon having an etched surface. However, RAU (col. 1, lines 32-45) discloses etching as a conventional method to make a balloon catheter. In view of RAU, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make NODDIN balloon catheter by an etching process as the etching process to make a balloon catheter is well known.

Response to Amendment

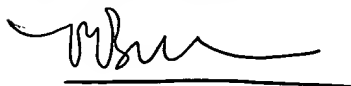
The arguments of the applicants have been carefully considered but are moot in view of new grounds of rejections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Vy Q. Bui
1/2/2004.